

**Urgent Field Safety Notice (FSN)**  
**ELAN 4 FIXED DURAGUARD**

For Attention of: **Users, Importers and Distributors of the affected products.**

Contact details of local representative (name, e-mail, telephone, address etc.)

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Dear Customer,

Aesculap AG as a legal manufacturer has voluntarily decided to recall the affected products under point 1.7 as a precaution due to the risk scenario mentioned below.

| <b>1. Information on Affected Devices</b> |   |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
|---|---|--------------------|-----------------------|--|------------------------|---------------------|--------------------|-----------------------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|--------|---------------------------------|----------|------|
| 1.1                                       | <b>Device Type</b>  |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
|   | ELAN 4 FIXED DURAGUARD  |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| 1.2.                                      | <b>Commercial names</b>   |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
|   | ELAN 4 FIXED DURAGUARD STANDARD<br>ELAN 4 FIXED DURAGUARD LONG  |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| 1.3.                                      | <b>Unique Device Identifier</b>   |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
|   | 40392390000028222X  |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| 1.4.                                      | <b>Primary clinical purpose of devices</b>  |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
|   | The ELAN 4 FIXED DURAGUARDS are used to cover the tip of the craniotome cutter and protect the soft tissues from contact with the cutter tip.   |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| 1.5                                       | <b>Article numbers</b>  |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
|   | GB942R; GB943R  |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| 1.6                                       | <b>Software version</b>   |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
|   | N/A   |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| 1.7                                       | <b>Affected serial and lot numbers</b>  |                    |                       |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
|   | <table border="1"> <thead> <tr> <th><b>Article Numbers</b></th> <th><b>Device Names</b></th> <th><b>Lot Numbers</b></th> <th><b>Serial Numbers</b></th> </tr> </thead> <tbody> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8112</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8113</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8114</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8115</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8116</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8117</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8118</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8119</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8120</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8121</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8122</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8123</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8124</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8125</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8126</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8127</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8128</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8129</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8130</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8131</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8132</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8133</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8134</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8135</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8136</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8138</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8140</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8141</td></tr> <tr><td>GB942R</td><td>ELAN 4 FIXED DURAGUARD STANDARD</td><td>52982936</td><td>8143</td></tr> </tbody> </table> |                    |                       |  | <b>Article Numbers</b> | <b>Device Names</b> | <b>Lot Numbers</b> | <b>Serial Numbers</b> | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8112 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8113 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8114 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8115 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8116 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8117 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8118 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8119 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8120 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8121 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8122 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8123 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8124 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8125 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8126 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8127 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8128 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8129 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8130 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8131 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8132 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8133 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8134 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8135 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8136 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8138 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8140 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8141 | GB942R | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8143 |
| <b>Article Numbers</b>                    | <b>Device Names</b>   | <b>Lot Numbers</b> | <b>Serial Numbers</b> |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8112                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8113                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8114                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8115                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8116                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8117                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8118                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8119                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8120                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8121                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8122                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8123                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8124                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8125                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8126                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8127                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8128                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8129                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8130                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8131                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8132                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8133                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8134                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8135                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8136                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8138                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8140                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8141                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |
| GB942R                                    | ELAN 4 FIXED DURAGUARD STANDARD   | 52982936           | 8143                  |  |                        |                     |                    |                       |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |        |                                 |          |      |

|     |                           |                                 |          |      |
|-----|---------------------------|---------------------------------|----------|------|
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8145 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8147 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8150 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8152 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8153 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8154 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8155 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8156 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8157 |
|     | GB942R                    | ELAN 4 FIXED DURAGUARD STANDARD | 52982936 | 8158 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4485 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4486 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4494 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4495 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4498 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4500 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4502 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4504 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4510 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4511 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4512 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4519 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4521 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4522 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4526 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4527 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4528 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4530 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4531 |
|     | GB943R                    | ELAN 4 FIXED DURAGUARD LONG     | 52983202 | 4533 |
| 1.8 | <b>Associated devices</b> |                                 |          |      |
|     | N/A                       |                                 |          |      |



## 2. Reason for Field Safety Corrective Action (FSCA)

|     |   |
|-----|---|
| 2.1 | <b>Description of the product problem</b>   |
|     | During the product realization process, there was a mix-up between the article numbers GB942R and GB943R. GB942R was incorrectly labeled as GB943R, and vice versa. Therefore, the ELAN 4 FIXED DURAGUARD STANDARD was labeled as "Long" and the ELAN 4 FIXED DURAGUARD LONG was labeled as "Standard".   |
| 2.2 | <b>Hazard giving rise to the FSCA</b>   |
|     | Due to the described product issue, it may mistakenly occur during application that an ELAN 4 FIXED DURAGUARD LONG is used with a standard craniotome cutter. Although a mechanical connection between these components is possible, the differing dimensions of the cutter prevent the intended craniotomy from being performed. The user might incorrectly assume a correct configuration and apply additional force without achieving the desired effect. Typically, this leads to the product being removed from the sterile field and subjected to inspection. |

|            |   |
|------------|---|
|            | <p>In contrast, an ELAN 4 FIXED DURAGUARD STANDARD is not compatible with a long craniotome cutter. This incompatibility is identified during intraoperative preparation, as a physical coupling of the components is not possible.</p> <p>In both cases, the user may be forced to resort to alternative products or procedures to successfully complete the craniotomy. This can result in a delay in the surgical workflow.</p>  |
| <b>2.3</b> | <b>Probability of problem arising</b>   |
|            | <p>Within the past five years (06.08.2020 - 06.08.2025), 13 products were reported with the described product problem for the ELAN 4 FIXED DURAGUARD. This corresponds to an actual failure rate of 0.00066%. Accordingly, in the product risk analysis, the anticipated probability of occurrence is assessed as "improbable" (&lt; 0.05%). Although the occurrence rate of the described issue remains within an acceptable range, the associated hazardous situation does not permit continued use of the affected products.</p> |
| <b>2.4</b> | <b>Predicted risk to patient/users</b>  |
|            | <p>The prolongation of the procedure combined with the need for additional handling and product changes, increases the risk of contamination and the likelihood of intraoperative complications, such as unintentional dural injury or bleeding.</p> <p>The overall potential severity to patients is classified as "serious".</p>  |
| <b>2.5</b> | <b>Further information to help characterise the problem</b>   |
|            | N/A   |
| <b>2.6</b> | <b>Background on Issue</b>  |
|            | N/A   |
| <b>2.7</b> | <b>Other information relevant to FSCA</b>   |
|            | N/A   |

|            |  |   |
|------------|--|---|
|            | <b>3. Type of Action to mitigate the risk</b>  |   |
| <b>3.1</b> | <b>Action To Be Taken by the User</b>  |   |
|            | Identify Device <input checked="" type="checkbox"/><br>Return Device <input checked="" type="checkbox"/> |   |
| <b>3.2</b> | <b>By when should the action be completed?</b>   | The Aesculap AG plans to complete this FSCA within the next 6 months. |
| <b>3.3</b> | <b>Is follow-up of patients or review of patients' previous results recommended?</b>                     |   |
|            | No   |   |
| <b>3.4</b> | <b>Is customer reply required?</b>   | Yes. See point 4.3  |
| <b>3.5</b> | <b>Action Being Taken by the Manufacturer</b>  |   |
|            | The affected products are recalled.  |   |

|     |  |    |
|-----|--|----|
| 3.6 | Is the FSN required to be communicated to the patient /lay user?   | No |
| 3.7 | If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? |    |
|     | N/A  |    |

| 4. General Information   |  |  |
|--|--|--|
| 4.1  | FSN Type   | New  |
| 4.2  | <b>Manufacturer information</b><br>(For contact details of local representative refer to page 1 of this FSN) |  |
|  | Company Name   | Aesculap AG  |
|  | Address  | Postfach 40, 78501 Tuttlingen  |
|  | Website address/Homepage   | <a href="http://www.aesculap.de">http://www.aesculap.de</a>  |
| 4.3  | List of attachments/appendices:  | Feedback Form<br>Return Form   |
| 4.4  | Name/Signature   | <br><b>Ms Chan Jeh Huei</b><br>Manager – Regulatory Affairs               |
|  | Name/Signature   | <br><b>Mr Muhammad Zaim Mohd Shairy</b><br>Executive – Regulatory Affairs |
| <b>Transmission of this Field Safety Notice (FSN)</b>  |  |  |
| <p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.<br/>(As appropriate)</p> <p>Please transfer this notice to other organisations on which this action has an impact.<br/>(As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> |  |  |

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| <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.</p> |
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