B. Braun Closure Technologies

Manipler®AZ-35W

Description

The Manipler®AZ is a sterile, single use skin stapler designed to deliver 36 stainless steel staples for routine wound closure.

Indications

The Manipler®AZ skin stapler can be used for routine skin closure in a wide variety of surgical procedures.

Applications

- Prior to using the skin stapler verify compatibility of skin staple remover.
- Using sterile technique remove the skin staple from the package.
- With a tissue forceps, pull skin edges together until edges evert (Fig.1)
- Position the skin stapler over the center of the everted skin edges (Fig.2)
- To form the staple, squeeze the trigger firmly together until the trigger motion is halted (Fig.3)
- Release the trigger (Fig.4)
- Move the staple off the incision (Fig.5)
- Always verify the correct position of the staple.

Contra-Indications

- When it is not possible to maintain at least 5mm distance from the stapled skin to underlying bones, vessels, or internal organs, the use of staples for skin closure is contraindicated.
- The Manipler®AZ staples contain nickel, which might lead to allergic reactions with some patients.
- Do not reuse or resterilize. This may cause damage on functional capacities of the product and product may cause damage or infection in patients.

Adverse Reactions

Adverse effects associated with the use of this device include: wound dehiscence; allergic response in patients with known sensitivities to metals contained in 316L stainless steel, (i.e., chromium, nickel and iron) enhanced bacterial infectivity; minimal acute inflammatory tissue reaction; and pain, edema, and erythema the wound site.

Precaution for use

The staple of Manipler®AZ is MR Conditional.

A) Non-clinical testing demonstrated that the staple of Manipler®AZ is MR Conditional.

- A patient with this device can be scanned safely, immediately following the following conditions:
  - Static magnetic field of 3 Tesla or lower
  - Maximum spatial gradient magnetic field of 1,500 G/cm (extrapolated) or less
  - Maximum MR system power: Whole body averaged specific absorption rate (SAR) of 4W/kg for 15 minutes of scanning (i.e., per pulse sequence)
  - Normal operating mode of operation for the MR system

B) MRI-Related Heating

In non-clinical testing, the staple of Manipler®AZ produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in a 3-Tesla MR system (Siemens 1.5T, Excite, HDx, Software 14X.06, General Electric Healthcare, Milwaukee, WI).
MR system reported, whole body averaged SAR 2.4W/kg
Calorimetry measured values, whole body averaged SAR 2.4W/kg
Highest temperature change 1.8°C
Temperature scaled to whole body averaged SAR of 4W/kg 2.5°C

C) Artifact Information
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Staple of Manipler®AZ. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 15-mm relative to the size and shape of the Staple of Manipler®AZ.

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>271mm²</td>
<td>175mm²</td>
<td>651mm²</td>
<td>467mm²</td>
</tr>
<tr>
<td>Plane Orientation</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Safety instructions
- Do not use the Manipler®AZ if the date of expiry has passed.
- Store the Manipler®AZ at room temperature and use it directly after the package has been opened.
- Never use products from open or damaged sterile packaging.
- Do not re-use, as this might impair the functioning of the product and injure the patient.
- Use the Manipler®AZ skin stapler only on one patient.
- After using, dispose of the product properly as medical waste.

Sterility
Sterilization is effective until the date of expiry, if the package is stored correctly in a closed and intact package.
Shelf life is 6 years.

Delivery formats and package sizes
The Manipler®AZ -35W is delivered in a box of 6 units.

Explanation of the symbols on the packaging

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Single use</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Use by date</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Sterilized by ethylene oxide</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>CE marking and identification number of notified body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Lot number</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>See instructions for use</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Catalogue number Art no. 783100</td>
</tr>
<tr>
<td><img src="image" alt="Symbol" /></td>
<td>Staple size 6.9 mm x 4.2 mm</td>
</tr>
</tbody>
</table>

Date of information 02/2016

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CE 0123

CE marking according to directive 93/42/EEC

Technical alterations reserved

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