### ENDOTINE Midface B 4.5

#### Instructions for Use

**DESCRIPTION**

The ENDOTINE Midface™ B 4.5 consists of bioabsorbable implants: a fixation platform (1A) and two screw anchors (1B). The implants are supplied sterile for single use only. Insertion tools are supplied separately. Installation of the ENDOTINE Midface™ B 4.5 requires the use of Instrument Kit, CFD-020-4320, which is supplied separately.

**INDICATIONS**

The ENDOTINE Midface™ B 4.5 is indicated for use in subperiosteal midface suspension surgery to fixate the cheek subdermis in an elevated position from the infra-orbital rim or zygoma via an anchoring leash and maintain fixation until healing has occurred.

**CONTRAINDICATIONS**

1. Situations where internal fixation is otherwise contraindicated (e.g., infection).
2. Patients appearing to have very thin soft tissues of the midface.
3. Any known allergy or foreign-body sensitivities to plastic biomaterial.

**PACKAGING, LABELING and STERILIZATION**

The ENDOTINE Midface™ B 4.5 implant components are supplied pre-sterilized by gamma irradiation and intended for single use only. DO NOT resterilize these devices. The devices should be accepted only if the factory packaging and labeling arrive intact. Do not use if packaging shows evidence of puncture(s), tampering, water contamination or other damage.

**STORAGE INSTRUCTIONS**

Store at room temperature (15 to 24°C or 60 to 75°F) in a dry place out of direct sunlight. Do not use beyond the expiration date listed on the outer label. Do not use if the temperature indicator on the carton has turned black; the indicator changes color if the device is subjected to temperatures that could damage it, even if the exposure is of short duration, as might occur during transportation.

**INSTRUCTIONS FOR USE**

1. Place your finger over the screw anchor while trimming to constrain the remnant. Discard trimmed portion.
2. Two cuts are required to trim the excess leash. While holding the clipper tool perpendicular to the bone, make each cut between the hole above the screw anchor and the outside edge of the leash (Figure 11).
3. The device will likely be palpable prior to absorption. Some devices may require removal prior to full absorption due to discomfort, excessive palpability, infection, allergic reaction or other concerns.
4. Transient local fluid accumulation and/or sinus formation may occur. Aspiration may yield traces of implant material and may result in healing of the sinuses without adverse effects.
5. Atraumatic tines may not penetrate tissues that have been scarred by prior trauma or surgery.

**PRECAUTIONS**

1. Inform the patient of possible adverse effects, including discomfort, visibility of the device under the skin, and surgical risks (such as nerve injury, facial musculature dysfunction, infection, scarring, device erosion through the skin, asymmetry, loss of suspension/elevation, etc.). The device will likely be palpable prior to absorption. Some devices may require removal prior to full absorption due to discomfort, excessive palpability, infection, allergic reaction or other concerns.
2. Discard open, unused devices.
3. This device is for SINGLE USE ONLY and MUST NEVER BE RE-USED. Resterilization may cause loss of function or failure of the device. Risks of re-use may include patient infection due to lack of sterility.
4. Inspect all components for damage before use. Do not attempt to repair damaged components.
5. Do NOT over tighten the screw anchor during installation.

**ADVERSE EFFECTS**

Material sensitivity/allergic reactions in patients following surgery should be reported. Implantation of foreign materials in tissues can result in histological reactions. Caution: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

---

### Table: ENDOTINE Midface™ B 4.5 Instrument Kit, CFD-020-4320

<table>
<thead>
<tr>
<th>Part No.</th>
<th>Tine Length</th>
<th>Part Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFD-020-0197</td>
<td>4.5 mm</td>
<td>ENDOTINE Midface™ B 4.5</td>
</tr>
<tr>
<td>CFD-020-4320</td>
<td>Drill Bit, 1.25mm</td>
<td>ENDOTINE Midface™ B Instrument Kit, CFD-020-4320</td>
</tr>
<tr>
<td>CFD-020-4200</td>
<td>Tap Tool</td>
<td>ENDOTINE Midface™ B Instrument Kit, CFD-020-4320</td>
</tr>
<tr>
<td>CFD-020-4250</td>
<td>Insertion Tool</td>
<td>ENDOTINE Midface™ B Instrument Kit, CFD-020-4320</td>
</tr>
<tr>
<td>CFD-020-4400</td>
<td>Clipper Tool</td>
<td>ENDOTINE Midface™ B Instrument Kit, CFD-020-4320</td>
</tr>
<tr>
<td>CFD-020-4325</td>
<td>Sterilization Tray</td>
<td>ENDOTINE Midface™ B Instrument Kit, CFD-020-4320</td>
</tr>
</tbody>
</table>