UNIVERSAL SHAPERS

Instruction for Use:

1. Device Description & Intended Use

Scalloping Drills (also referred to as **SS drills**) are rotary surgical instruments designed to sculpt or "scallop" the alveolar crest and adjacent cortical bone to form a "bedding" or "release ring" around an implant site. They serve to contour bone, relieve crestal stress, and create favorable architecture for restorative components.

They are intended for use in oral implant surgeries in conjunction with other drills (pilot, twist, cortical release, etc.) as part of the bone preparation / profiling sequence.

2. Indications

- Sculpting or profiling of the alveolar crest to match prosthetic contours
- Creation of a "bedding" or anatomical shape around multi-unit abutments or prosthetic bases
- Assisting in forming a cortical "release ring" to relieve compressive stress at the coronal bone interface
- Use in sinus window shaping (lateral sinus approach) because of the curved / scalloped geometry for safer cortical opening

3. Contraindications / Limitations

- Do not use in patients contraindicated for implant surgery (e.g. ineffective healing, uncontrolled systemic disease)
- Do not use in non-sterile environments
- Not intended to replace primary osteotomy drills
- Do not exceed the mechanical fatigue life of the instrument (as determined by the manufacturer)
- Do not use if the drill is damaged, bent, chipped, or worn

4. Warnings & Precautions

- Must be used by trained implant surgeons
- Use copious sterile irrigation to avoid heat generation and thermal damage to bone
- Employ an intermittent (pecking) technique, avoiding continuous force
- Ensure correct alignment in the osteotomy before engaging the scalloping segment
- Avoid inadvertent contact with soft tissues or adjacent structures
- Inspect the drill before each use for signs of wear, cracks or debonding
- Prevent the instrument from being aspirated or swallowed during surgery

5. Instructions for Use

5.1 Preoperative Preparation

1. Sterilize the scalloping drills using a validated protocol.
2. Visually and microscopically inspect for damage, corrosion, or irregularities.
3. Confirm packaging integrity and traceability (lot, serial, etc.).
4. Select the appropriate scalloping drill size / shape consistent with your surgical plan.

5.2 Surgical Use

1. Complete the primary osteotomy steps (pilot drill, twist drills, etc.) to the desired depth.
2. Position the scalloping drill into the osteotomy carefully, ensuring concentric alignment with the site.
3. Recommended rotational speed is similar to implant profile and profiling drills (depending on bone density) for example, moderate speeds with irrigation (exact rpm should follow the implant system standards).
4. Under sterile irrigation, gently advance the scalloping drill into the site, sculpting the cortical margins in a controlled manner.
5. Use a pecking or light up-and-down motion to promote controlled removal; do *not* force or torque aggressively.

6. Continue until the desired scalloped geometry or cortical contour is achieved.
7. Withdraw the drill while irrigating.
8. Proceed with any subsequent steps (e.g. cortical release drill, countersink, implant insertion) per your protocol

5.3 Postoperative Handling & Reuse

1. Immediately rinse to remove gross debris using sterile saline.
2. Clean thoroughly (e.g. ultrasonic bath, enzymatic detergent) following your validated reprocessing procedure.
3. Dry meticulously and inspect for wear, microcracks, or damage.
4. Sterilize before reusing.
5. Maintain logs tracking number of uses; discard when surpassing limit or when damage is observed.

6. Performance / Safety Considerations

- Proper scalloping reduces bone compression at the crest and helps optimize prosthetic seating
- Controlled contouring helps maintain biologic width and reduce marginal bone resorption
- Use of scalloping in conjunction with cortical release improves stress distribution around implants

7. Storage

- Store in original or dedicated instrument trays
- Avoid humid, corrosive, or dirty conditions
- Keep packaged sterile until time of use

8. Symbols & Labeling

- Indicate part number, size, batch/lot number, sterilization status, reuse limits
- Use standard symbols: “Single instrument lifetime,” “Sterile unless opened/damaged,” “Do not use if package damaged”

9. Troubleshooting & Disposal

- If the drill binds, withdraw and inspect for debris or obstruction
- If the scalloped edges become dull, chip, or crack, discontinue use
- Dispose of failed or end-of-life drills per regulated medical sharps / metal instrument waste protocol

Symbol	Reference No. EN ISO 15223-1, Section	Title – Symbol Description
	5.1.1	Manufacturer – Indicates the medical device manufacturer.
	5.1.3	Date of Manufacture – Indicates the date (YYYY-MM-DD) when the medical device was manufactured.
	5.1.5	Lot Number – Indicates the manufacturer’s batch code so that the lot can be identified.
	5.1.6	Catalogue Number – Indicates the manufacturer’s catalogue number so that the medical device can be identified.
	5.4.3	Consult Instruction for Use. Indicates the need for the user to consult the Instructions for Use.
	5.4.4	Caution – Indicates the user needs to consult the instructions for use for important cautionary information such as warnings and precautions.