

2022 Coding and Reimbursement Guidelines for HEMIGARD® ASRD and SUTUREGARD® ISR Devices

The following information is shared for educational purposes only. While SUTUREGARD® Medical believes this information to be correct, coding and reimbursement decisions by AMA, CMA and payers are subject to change. Thus, providers should discuss appropriate coding and reimbursement with their payers.

FDA Regulatory Clearance:

The HEMIGARD® ASRD and SUTUREGARD® ISR devices are both FDA registered as suture retention devices (21 CFR § 878.4930).

The HEMIGARD® ASRD device is intended to support a retention suture in a wound closure and be retained up to two weeks postoperatively.

The SUTUREGARD® ISR device is intended to support a retention suture intraoperatively to facilitate skin relaxation and be retained up to 2 hours (though, most effect is seen within 30 minutes).

Value Analysis Significance:

In multiple clinical trials, HEMIGARD® adhesive suture retention device (ASRD) has been shown to reduce post-operative wound dehiscence by 79-89%. For many orthopedic, vascular, and general surgery procedures, dehiscence can be a devastating and costly complication. In amputations, adoption of HEMIGARD® ASRD for all cases resulted in a cost savings of \$9940 per case. HEMIGARD® ASRD has also been shown to reduce postoperative dehiscence in the setting of orthopedic trauma, where dehiscence results in exposed hardware and potential costly return to the OR.

A typical Facility surgical case involving HEMIGARD® ASRD would have 3-6 units (pouches) of HEMIGARD® ASRD per case. There are TWELVE (12) pouches per box, meaning that 2-4 surgical cases could be performed using a single box of HEMIGARD® ASRD.

Coding Considerations:

Coders provide a uniform language for describing services rendered by health providers. The selection of codes depends on the precise details and necessity of the surgical procedure. It is the sole responsibility of the health care provider to correctly prepare claims submitted to insurance companies and other payers.

Physician's Professional Fee:

Fulfilling complex repair requirements is possible with the **HEMIGARD® ASRD** and **SUTUREGARD® ISR devices when the devices are used to place a retention suture** and all other requirements are met. The HEMIGARD® ASRD and SUTUREGARD® ISR are classified by the U.S. Food & Drug as **suture retention devices** (Sec. 878.4930).

Complex repair (CPT® codes 13100 to 13160) includes the repair of wounds that, in addition to the requirements for intermediate repair, require at least one of the following: exposure of bone, cartilage, tendon, or named neurovascular structure; debridement of wound edges (e.g., traumatic lacerations or avulsions); extensive undermining (defined as distance equal to or greater than the maximum width of the defect, measured perpendicular to the closure line along at least one entire edge of the defect); involvement of free margins of helical rim, vermilion border, or nostril rim; **placement of retention sutures**. Necessary preparation includes creation of a limited defect for repairs or the debridement of complicated lacerations or avulsions. Complex repair does not include excision of benign (11400-11446) or malignant (11600-11646) lesions, excisional preparation of a wound bed (15002-15005), or debridement of an open fracture or open dislocation.

CPT® code	Description	National Payment Amount*	
		Non-Facility	Facility
13160	Secondary closure of surgical wound, extensive or complicated	N/A	\$815.32
13101	Complex repair to the trunk of 2.5cm to 5.0cm	\$411.81	\$250.90
13102	Complex repair to the trunk; each additional 5.0cm or less	\$120.78	\$73.36
13121	Complex repair to the scalp, arms and/or legs of 2.5cm to 5.0cm	\$439.85	\$259.55
13122	Complex repair to the scalp, arms and/or legs; each additional 5.0cm or less	\$130.81	\$83.40
13132	Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet of 2.5cm to 5.0cm	\$486.91	\$305.57
13133	Complex repair to forehead, cheeks, chin, mouth, neck, axillae, hands and/or feet; each additional 5.0cm or less	\$172.34	\$126.31
13152	Complex repair to eyelids, nose, ears and/or lips of 2.5cm to 5.0cm	\$512.86	\$338.80
13153	Complex repair to eyelids, nose, ears and/or lips; each additional 5.0cm or less	\$189.99	\$138.43

*Based on 2022 values (www.cms.gov)